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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,080	01/23/2001	David A. Estell	GC527C3	2502
5100	7590	04/19/2004	EXAMINER	
GENENCOR INTERNATIONAL, INC. ATTENTION: LEGAL DEPARTMENT 925 PAGE MILL ROAD PALO ALTO, CA 94304			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/768,080	Applicant(s) ESTELL ET AL.	
	Examiner David A Saunders, PhD	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-10, 14 and 15 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-10, 14 and 15 is/are allowed.
- 6) ☒ Claim(s) 7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Claims 7-10 and 14-15 are pending. Claims 7-10 and 14-15 are under examination.

Applicant is advised that the Notice of Allowance mailed 2/9/04 is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

Prosecution on the merits of this application is reopened on claim 7, which is considered unpatentable for the reasons indicated below:

Upon reconsideration of prior art cited in copending applications, it is deemed claim 7 is not in condition for allowance.

Claim 7 is rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Wells et al (EP 0,251,446) or its equivalent Bott et al (5,801,038).

Bott et al disclose (Table II at col. 15 of '038) that substitution of Tyr 171 with Gln provides an expected useful mutation in subtilisin from *B. amyloliqueofaciens*. This change corresponds to the instant embodiment (as disclosed at page 20, line 29) involving Y171Q.

Rejection is made on the basis that the substituted subtilisin of Bott et al would inherently be less allergenic than the native form of the enzyme, based upon applicant's own teachings. Even though the substitution taught by Bott et al may not have been arrived at in the same manner or for the same purpose as instantly, the product is the same claimed product no matter what reason motivated its production.

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Claim 7 is rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Siekstra et al (WO 96/34946) or (5,837,517).

Like Wells et al and Bott et al, Siekstra et al disclose ('517 at col. 15, line 23) various substituted subtilisins, including those having the single substitution Y171Q, as disclosed at instant page 20, line 29.

Upon further consideration it is also deemed that an obviousness type double patenting rejection should be stated:

Claim 7 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,596,525. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims cover an enzyme of reduced allergenicity by virtue of having one or more amino acid substitutions within a T-cell epitope; the issued claims cover a protease (a subgenus of enzymes) of reduced allergenicity by virtue of having two or more amino acid substitutions within a T-cell epitope. Since "one or more" encompasses "two or more" the claims clearly embrace common subject matter. Disclaimer is required to assure that common ownership will be maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon-Thu from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 4/13/04 DAS

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
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